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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,872	05/26/2000	Jeffrey Steven Albrecht	00JSA001	9690

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EXAMINER

GILLIGAN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/579,872

Applicant(s)

ALBRECHT, JEFFREY STEVEN

Examiner

Luke Gilligan

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. In the amendment filed 12/10/04, the following has occurred: no claims have been added, amended, nor canceled. Now, claims 21-43 are presented for examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 41 recites the limitation "the unforeseen event" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no previous recitation of "an unforeseen event" other than "unforeseen self administration of a medical treatment." Since claim 41 defines "the unforeseen event" as an accident, which is clearly not a form of self administration of a medical treatment, it is unclear what "the unforeseen event" is referring to.

5. Similarly, claims 42 and 43 respectively define "the unforeseen event" as a "medical symptom" and a "physical reaction" which are also not forms of self administration of a medical treatment. Therefore, there is insufficient antecedent basis for "the unforeseen event" limitation in these claims as well.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 3626

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 21-25, 27-28, 31-32, and 35-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, U.S. Patent No. 6,161,095 in view of Kehr, U.S. Patent No. 5,642,731.

8. As per claim 21, Brown teaches a medical management system comprising: a personal communication device programmed to allow a patient to generate a record indicating a patient initiated decision to self administer a medical treatment (see column 5, lines 3-34); a database (see column 6, lines 48-57); a network coupling the personal communication device and the database to allow information to pass between the personal communication device and the database (see column 3, line 63 – column 4, line 6); wherein, the record generated includes a time the medical treatment was administered and additional information about the medical treatment administered (see column 5, lines 24-40); wherein, the personal communication device sends the record to the database over the network (see column 3, line 63 - column 4, line 6 and column 5, lines 48-57); and wherein the record is added to the database (see column 5, lines 48-57).

9. Brown does not explicitly teach generating, by a patient, a record of the patient's unforeseen self administration of a medical treatment. Kehr teaches a personal communication device that is programmed for generating, by a patient, a record of the patient's unforeseen self administration of a medical treatment (see column 15, lines 10-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Brown. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of providing enhanced patient care by providing greater communication between provider and patient especially with respect to unscheduled treatments as suggested by Kehr (see column 4, lines 14-20 of Kehr).

Art Unit: 3626

10. As per claim 22, Brown in view of Kehr teach the method of claim 21 as described above. Brown further teaches a part of the record is interactively generated by input from the patient and a part of the record is automatically generated by the personal communication device (see column 5, lines 24-40).

11. As per claim 23, Brown in view of Kehr teach the method of claim 21 as described above. Brown further teaches wherein the database is processed to initiate an automatic medication reorder (see column 3, lines 3-6 and column 4, line 43 – column 5, line 14).

12. As per claims 24 and 25, Brown in view of Kehr teaches the method of claim 21 as described above. Brown further teaches one or more communications devices coupled to the network and programmed to allow healthcare providers and pharmacists to access the database and to communicate with patients (see column 3, line 63 – column 4, line 34 and column 7, line 63 – column 8, line 19).

13. As per claim 27, Brown in view of Kehr teach the method of claim 21 as described above. Brown does not explicitly teach receiving warning messages through the personal communication device indicating that the patient possesses tainted medication. Kehr teaches receiving warning messages through a personal communication device indicating that the patient possesses tainted medication (see column 22, lines 42-53). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Brown for the reasons given above with respect to claim 21.

14. As per claim 28, Brown in view of Kehr teach the method of claim 21 as described above. Brown further teaches wherein the database contains patient education material accessible to the patient (see column 4, lines 46-48 and column 4, line 57 – column 5, line 23; the examiner interprets “treatment regimen” information as a form of “education material”).

Art Unit: 3626

15. As per claim 31, Brown in view of Kehr teach the method of claim 21 as described above. Brown further teaches wherein the database is used to perform tracking and trending of medication administered by the patient (Brown; col. 2, line 66-col. 3, line 3 and col. 6, lines 8-14).

16. As per claim 32, Brown teaches a personal interactive medication logging apparatus comprising: a processor (see column 4, lines 35-42); a memory (see column 4, lines 35-42); a communications interface (see column 4, lines 52-57); a user interface to receive input from a patient and present information to the patient (see column 4, lines 35-42); software stored in the memory and executable on the processor for performing functions comprising: generating a record in response to patient input received from the user interface, wherein the record indicates a patient initiated decision to self administer a medical treatment (see column 5, lines 24-40); and the time the medical treatment was administered (see column 5, lines 24-40); and using the communications interface to transmit the record to a central database, outside the personal interactive medication logging apparatus (see column 5, lines 48-57); and using the communications interface to receive messages from medical professionals (see column 3, line 63 – column 4, line 51).

17. Brown does not explicitly teach generating, by a patient, a record of the patient's unforeseen self administration of a medical treatment and symptoms that preceded the treatment. Kehr teaches a personal communication device that is programmed for generating, by a patient, a record of the patient's unforeseen self administration of a medical treatment (see column 15, lines 10-24) and symptoms that preceded the treatment (see column 4, lines 14-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Brown. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of providing enhanced patient care by

Art Unit: 3626

providing greater communication between provider and patient especially with respect to unscheduled treatments as suggested by Kehr (see column 4, lines 14-20 of Kehr).

18. As per claim 35, Brown in view of Kehr teach the database of claim 32 as described above. Brown further teaches the software is further capable of retrieving patient education material from the database via the communications interface (see column 4, lines 46-48 and column 4, line 57 – column 5, line 23).

19. Claims 36-38 recites substantially similar limitations to those already addressed in claim 21, 27 and 31 and, as such, is rejected for similar reasons as given above.

20. As per claim 39, Brown in view of Kehr teach the database of claim 36 as described above. Brown does not explicitly teach an experience that triggered symptoms and a response to treatment. Kehr teaches an experience that triggered symptoms and a response to treatment (see column 3, line 48 – column 4, line 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Brown for the reasons given above with respect to claim 21.

21. Claim 40 recites substantially similar limitations to those already addressed in claim 21 and, as such, is rejected for similar reasons as given above.

22. As per claim 41-43, Brown in view of Kehr further teach all of the limitations of claim 40 as described above, and further teach the limitations of claims 41-43 for the same reasons.

23. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, U.S. Patent No. 6,161,095 in view of Kehr, U.S. Patent No. 5,642,731 and further in view of Cummings, Jr. (5,301,105).

24. As per claim 26, Brown in view of Kehr teach the method of claim 21 as described above. Brown does not explicitly teach one or more communications devices coupled to the

Art Unit: 3626

network and programmed to allow insurance providers to access the database and to communicate with patients. However, this feature is old and well known in the art, as evidenced by Cummings' teachings with regards to one or more communications devices coupled to the network and programmed to allow insurance providers to access the database and to communicate with patients (see abstract and figure 1). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Brown with Cummings' teaching with regards to these limitations, with the motivation of providing patients with predetermined financial support (see abstract of Cummings).

25. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, U.S. Patent No. 6,161,095 in view of Kehr, U.S. Patent No. 5,642,731 and further in view of Halvorson, U.S. Patent No. 4,847,764.

26. As per claim 29, Brown in view of Kehr teach the method of claim 21 as described above. Brown does not explicitly teach the wherein the database contains a product catalog. However, this feature is old and well known in the art, as evidenced by Halvorson's teachings with regards to a database that includes a product catalog (see column 36, lines 60-66). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Brown with Halvorson's teaching with regards to this limitation, with the motivation of enhancing the inventory control of medications within the system of Brown (see column 2, lines 39-53 of Halvorson).

27. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, U.S. Patent No. 6,161,095 in view of Kehr, U.S. Patent No. 5,642,731 and further in view of

Art Unit: 3626

Campbell (Campbell, Sandy, "Accordant meets the challenges that rare chronic diseases pose for managed care," Health Care Strategic Management, August 1996).

28. As per claim 30, Brown teaches that the patient treatment regimen and protocol are stored in a database (Brown; col. 4, lines 43-48), but fails to expressly teach the database is tailored to the disease hemophilia. However, this feature is old and well known in the art, as evidenced by Campbell's teachings with regards to a database consisting of protocols and algorithms for treatments for diseases including hemophilia (Campbell; abstract). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Brown with Campbell's teaching with regards to this limitation, with the motivation of providing treatment regimens and protocols for patients suffering from hemophilia, thereby meeting disease management objectives (Campbell; abstract).

29. Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, U.S. Patent No. 6,161,095 in view of Kehr, U.S. Patent No. 5,642,731 and further in view of Glynn, U.S. Patent No. 5,774,865.

30. As per claim 33, Brown in view of Kehr teaches the method of claim 32 as describe above. Brown does not explicitly teach a bar code reader and wherein the software is further capable of accepting input from the patient via the user interface to activate the barcode reader and use the information retrieved from the barcode reader to add information to the record comprising the identity of a medication being taken by the patient as part of the medical treatment. However, this feature is old and well known in the art, as evidenced by Glynn's teachings with regards to a bar code reader and wherein the software is further capable of accepting input from the patient via the user interface to activate the barcode reader and use

Art Unit: 3626

the information retrieved from the barcode reader to add information to the record comprising the identity of a medication being taken by the patient as part of the medical treatment (see abstract and column 4, lines 32-56). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to incorporate this feature into the system of Brown. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of enhancing the accuracy of the record keeping in Brown.

31. As per claim 34, Brown in view of Kehr teaches the method of claim 32 as describe above. Brown does not explicitly teach wherein the software is further capable of automatically generating part of the record, and presenting the record to the patient for review prior to the record's transmission to the database. However, this feature is old and well known in the art, as evidenced by Glynn's teachings with regards to wherein the software is further capable of automatically generating part of the record, and presenting the record to the patient for review prior to the record's transmission to the database (see; abstract and column 4, lines 32-56). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to incorporate this feature into the system of Brown. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of enhancing the accuracy of the record keeping in Brown.

Response to Arguments

32. In the remarks filed 12/10/04, Applicant argues in substance that the combination of Brown and Barrett fail to teach certain features and that there is no motivation to combine the references. Applicant further argues that Goetz fails to teach certain features. These

Art Unit: 3626


arguments have been fully considered but are now moot in view of the new grounds of rejection presented above.

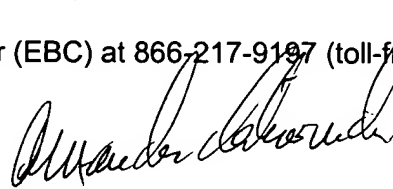
Conclusion

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (703) 308-6104. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

35. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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ALEXANDER KALINOWSKI
PRIMARY EXAMINER